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10/068,963	02/11/2002	Philip Rodney Kwok	P 290534	2378

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EXAMINER

EREZO, DARWIN P

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 08/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

TW

<b>Office Action Summary</b>	Application No. 10/068,963	Applicant(s) KWOK ET AL.	
	Examiner Darwin P. Erez	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 June 2005.  
 2a) ☒ This action is FINAL.                      2b) ☐ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 23-104 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) ☒ Claim(s) 32,33,36-39 and 96-99 is/are allowed.  
 6) ☒ Claim(s) 23-31,34,35,40-95 and 100-104 is/are rejected.  
 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to:  
 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/22/05</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 23-27, 30, 31, 34, 35, 40-47, 52, 53 62-75, 80, 81, 90-95 and 102-104 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,739,755 to White et al.

3. As to claim 23, White teaches a nasal mask cushion comprising a substantially triangular-shaped frame **18** having a rim to surround at least a portion of the wearer's nose (see Fig. 4-5); a membrane **12** of resilient material, the membrane being relatively more flexible than the frame (col. 3, lines 43-55) and being of the same generally shape as the rim and fixed to and extending away from the frame so as to have an outer surface spaced from the rim (Fig. 4), a portion of the outer surface forming a face contacting seal portion (Fig. 4); a nose receiving cavity bounded by the frame and the membrane (Figs. 1 and 5); wherein the face contacting seal portion is generally coterminous with respect to the rim and resiliently deformable towards the rim in use of the cushion (see Fig. 4); and wherein the membrane has a radius of curvature oriented towards the nose-receiving cavity (as exemplified in Fig. 1a, the membrane **12** has curves inward).

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4. As to claim 24, White teaches the membrane and the rim having a co-located notch to accommodate the bridge of the nose (Figs. 1 and 5).
5. As to claims 25 and 27, White teaches the membrane shaped so that the seal portion contacts the user's nose (Fig. 4).
6. As to claim 26, White teaches the membrane and the rim as substantially saddle shaped (Fig. 5).
7. As to claim 30, White teaches only the membrane contacting the user's face in use (Fig. 4).
8. As to claim 31, White teaches only a single seal (Fig. 4).
9. As to claim 34, White teaches a nasal mask cushion assembly comprising a generally triangularly shaped frame **18** of resilient material, the frame including a first side adapted to contact a mask body of the nasal mask (Fig. 4), a second side opposite the first side, an aperture extending from the first side to the second side (Figs 1A-1D), a rim on the second side extending around at least a portion of the perimeter of the aperture, and a notch in the rim in a region adapted to receive the bridge of the wearer's nose (Fig. 1 and 5); and a generally triangularly shaped membrane **12** of resilient material, the membrane including an aperture adapted to receive the wearer's nose (Fig. 5), an edge defining the perimeter of the aperture, a notch in a region adapted to receive the bridge of the wearer's nose (Fig. 5), a first surface including a seal forming portion disposed around the perimeter of the aperture adapted to deform and form a seal over a portion of the wearer's face in a region between the base of the nose and the upper the sides and over the bridge of the wearer's nose when the mask in use

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(Figs. 4 and 5), a second surface opposite the first surface that surrounds and is spaced a first distance from the rim of the frame in at least the region adapted to receive the bridge of the wearer's nose when the mask is in use (Fig. 4), wherein the membrane is more flexible than the frame (col. 3, lines 43-55).

10. As to claim 35, White teaches the frame and the membrane formed in a single piece (Fig. 4).

11. As to claims 40, 62, 68 and 90, White teaches a nasal mask cushion comprising: a nasal bridge region, a cheek region and a lip region (Figs 1 and 4); a first membrane **18** comprising a frame of resilient material having a side wall and first molded inwardly curved rim extending from the side wall (Fig. 4), said frame having a front portion with an edge molded to a mask body (Fig. 4); and a saddle shaped second membrane **12** of resilient material, the second membrane having a second molded inwardly curved rim (Fig. 4), the second membrane curved rim spaced a distance from the first molded inwardly curved rim (Figs. 1A-1D), the distance being greater than a thickness of the first molded inwardly curved rim (Figs. 1A-1D), the distance measured when the mask is not in use, a portion of the second membrane curved rim forming a face contacting seal (Fig. 4); wherein the second membrane curved rim is spaced sufficient distance from the first membrane curved rim such that under a normal tightening force of the mask to the wearer's face, at least a portion of the second membrane curved rim remains spaced from the first membrane curved rim (Fig. 4); and wherein the second molded inwardly curved rim has a curvature oriented to present a generally convex sealing surface to the wearer's face in use (Fig. 1a, see **12**).

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12. As to claims 41, 63, 69 and 91, White teaches the second membrane being conformable to various facial structures due to its flexibility (col. 3, lines 43-55).

13. As to claims 42, 43, 64, 65, 70, 71, 92 and 93, White teaches the maximum deformation of the second membrane being defined by the first membrane and wherein the maximum deformation position is not reached under normal tightening force of the mask to the wearer's face. It is inherent that the location of the first membrane will define how far the second membrane can deform.

14. As to claims 44, 66, 72 and 94, White teaches the first and second membrane formed as a one-piece unite (Fig. 4).

15. As to claims 45, 67, 73 and 95, White teaches the first membrane is thicker than the second membrane (col. 3, lines 43-55).

16. As to claims 46 and 74, White teaches a nasal mask comprising a mask body; a nasal cushion including a nasal bridge region, a cheek region and a lip region (Figs. 1 and 4); a substantially triangularly-shaped first membrane **18** of resilient material having a first molded inwardly curved rim; and a saddle-shaped second membrane **12** also of resilient material, the second membrane having a second molded inwardly curved rim (Fig. 4), the second molded rim being fixed to and extending away from the first membrane so as to have second membrane inner surface spaced a distance from an outer surface of the first molded rim (Figs. 1A-1D and 4), the distance greater than a thickness of the first molded inwardly curved rim (Figs 1A-1D), the first distance measured when the mask is not in use, a portion of the second molded rim forming a face contacting seal (Fig. 4); wherein the seal portion is substantially coterminous with

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respect to the second molded rim and is resiliently deformable towards the first membrane in use of the mask (Fig. 4); and wherein the first and second molded inwardly curved rims are curved generally towards the nose-receiving cavity (Fig. 1a).

17. As to claims 47 and 75, White teaches an arm (yoke) having an oblong slot (openings) to receive a strap (col. 5, lines 6-16).

18. As to claims 52 and 80, White teaches the first and second membrane formed as a one-piece unite (Fig. 4).

19. As to claims 53 and 81, White teaches the first membrane being thicker than the second membrane (Fig.4).

20. As to claim 102, White teaches a mask body having a plurality of vent openings  
8.

21. As to claims 103 and 104, White teaches the frame interengaging with the mask body, with the edge being non-planar and including a nasal bridge (Fig. 4).

### ***Claim Rejections - 35 USC § 103***

22. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

23. Claims 28, 29, 48-51 and 76-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over White et al. in view of US 5,243,971 to Sullivan et al.

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24. As to claims 28 and 29, White is silent with regards to the nasal cushion contacting the facial tissue between the base of the nose and the top lip. Sullivan teaches a nasal cushion having a sealing portion contacting the facial tissue around the sides and over the bridge of the nose, and between the base of the nose and the top lip. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the mask of White to only cover a user's nose, since nasal masks are well known in the art and more suitable for other applications like CPAP.

25. As to claims 48 and 76, White is silent with regard to a pad mounted on the arm and centered above the nasal bridge region of the mask. Sullivan teaches a nasal mask having an arm including a pad located above the nasal bridge region of the mask. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the arm of White to that of Sullivan since the arm of Sullivan stabilizes the nasal mask against the forehead of the user.

26. As to claims 49-51 and 77-79, White teaches the second membrane conformable to various facial structures with minimum force (col. 3, lines 43-52) and wherein maximum deformation of the second membrane being defined by the first membrane and wherein the maximum deformation position is not reached under normal tightening force of the mask to the wearer's face. It is inherent that the location of the first membrane will define how far the second membrane can deform.



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27. Claims 54, 55, 60, 61, 82, 83, 88, 89 100 and 101 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,148,802 to Sanders et al. and in view of US 4,739,755 to White et al.

28. As to claims 54 and 82, Sanders teaches all the limitations of the claim except for the nasal mask cushion having a first membrane of resilient material having a first membrane having a first molded inwardly curved rim; and a saddle-shaped second membrane having a second membrane being fixed to and extending away from the first membrane so as to have an inner surface spaced a distance from the first molded rim, the distance greater than a thickness of the first inwardly curved rim, the distance measured when the mask is not in use, a portion of the second molded rim forming a face contacting seal; wherein the seal portion is generally coterminous with respect to the second molded rim and is resiliently deformable towards the first membrane in use of the mask.

White teaches a nasal mask comprising a mask body; a nasal cushion including a nasal bridge region, a cheek region and a lip region (Figs. 1 and 4); a first membrane **18** of resilient material having a first molded inwardly curved rim; and a saddle-shaped second membrane **12** also of resilient material, the second membrane having a second molded inwardly curved rim (Fig. 4), the second molded rim being fixed to and extending away from the first membrane so as to have second membrane inner surface spaced a distance from an outer surface of the first molded rim (Figs. 1A-1D and 4), the distance greater than a thickness of the first molded inwardly curved rim (Figs 1A-1D), the first distance measured when the mask is not in use, a portion of the second molded

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rim forming a face contacting seal (Fig. 4); wherein the seal portion is substantially coterminous with respect to the second molded rim and is resiliently deformable towards the first membrane in use of the mask (Fig. 4); and wherein the seal portion fully covers the first molded inwardly curved rim so that the second inwardly curved rim is positioned to provide the only seal with the wearer's face, in use (the second rim can provide the only seal depending on the pressure applied to hold the mask on the user's face).

Therefore, it would have been obvious to one of ordinary skill in the art to modify the mask of Sanders to include the cushion and seal of White because it would have provided a more comfortable and leak-proof mask for the wearer, as disclosed by White.

29. As to claims 55 and 83, White teaches an arm (yoke) having an oblong slot (openings) to receive a strap (col. 5, lines 6-16).

30. As to claims 60, 61, 88 and 89, White teaches the first and second membrane formed as a one-piece unit (Fig. 4) and wherein the first membrane is thicker than the second membrane.

31. As to claim 100, White teaches a plurality of vent openings 8.

32. As to claim 101, White teaches the frame interengaging with the mask body, with the edge being non-planar and including a nasal bridge (Fig. 4).

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33. Claims 56-59 and 84-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sanders et al./White et al., and in further view of US 5,243,971 to Sullivan et al.

34. As to claims 56 and 84, White is silent with regard to a pad mounted on the arm and centered above the nasal bridge region of the mask. Sullivan teaches a nasal mask having an arm including a pad located above the nasal bridge region of the mask. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the arm of White to that of Sullivan since the arm of Sullivan stabilizes the nasal mask against the forehead of the user.

35. As to claims 57-59 and 85-87, White teaches the second membrane conformable to various facial structures with minimum force (col. 3, lines 43-52) and wherein maximum deformation of the second membrane being defined by the first membrane and wherein the maximum deformation position is not reached under normal tightening force of the mask to the wearer's face. It is inherent that the location of the first membrane will define how far the second membrane can deform.

#### ***Allowable Subject Matter***

36. Claims 32, 33, 36-39 and 96-99 are allowed.

#### ***Response to Arguments***

37. Applicant's arguments filed 6/2/05 have been fully considered but they are not persuasive.

With regards to claim 23, White teaches the membrane having a radius of curvature oriented towards the nose receiving cavity, as seen in Fig. 1a.

With regards to claim 34, White teaches a seal forming portion that is capable of deforming over a user's nose and upper lip. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

With regards to claims 40, 68, 74, see Fig. 1a.

With regards to claims 62 and 90, see Fig. 4.

With regards to the combination of Sanders and White, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, both references are in the same field of endeavor. Sanders teaches a system utilizing a mask. White teaches the mask. Furthermore, Sullivan is also in the same field of endeavor, which is providing respiratory gas to a user using a mask.

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***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erez who's telephone number is (571) 272-4695. The examiner can normally be reached on M-F (7:30-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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GLENN K. DAWSON  
PRIMARY EXAMINER